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Report from the U.S. Department of Health and Human Services—India

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Message from Ambassador David C. Mulford, Embassy of the United States of America
New Delhi

The U.S. and India are poised for a partnership that will be crucial in shaping the international order in the 21st century. The co-operation between our two countries expands and touches all aspects of a global community; including health and biomedical research, agriculture, civilian nuclear, high-technology trade, space, energy and economic and strategic elements. The Indo - U.S. partnership is continuing to meet the global health challenges that face today's world. The HHS India Office, representing the U.S. Department of Health and Human Services (HHS) in South Asia, is collaborating with India to increase scientific knowledge and control, prevent, and eliminate diseases. HHS India plays a pivotal role in this quest, and it is with great pleasure I write this message for the first issue of the quarterly newsletter "*U.S.– India Health News*," which I am sure will serve as a window of information on HHS activities. I wish the Newsletter success in this endeavor."



— Ambassador David C. Mulford, U.S. Embassy New Delhi



— Dr. Altaf Lal, Health Attaché and HHS Regional
Representative for South Asia, U.S. Embassy New Delhi

"*HHS India News*" seeks to inform the Department of Health and Human Services (HHS) and its agencies of the many activities of the HHS India Office in support of HHS agencies in biomedical research, biotechnology and disease control, prevention and elimination. As Health Attaché and HHS Regional Representative for South Asia, I am happy to send to our readers the first issue of the quarterly newsletter "*U.S.– India Health News*," which is a glimpse into our manifold activities. We look forward to your inputs and comments to further enrich our newsletter, and for your continued support of HHS India in its goal towards greater Indo-U.S. collaboration in biomedical research and public health programs. This newsletter is meant to provide information on HHS's Indo-U.S. collaborative programs to Indian and American scientists, health professionals, and policy makers in academia, government, non-governmental organizations, foundations, international and multi-lateral organizations, and industry."

ABOUT THE HHS INDIA OFFICE

The HHS India Office has grown to be vibrant and productive, working on behalf of HHS and its agencies on technical and policy matters. We assist Indian and American experts and researchers to establish and maintain collaborations and initiate new scientific projects and health programs. Today, Indo-U.S. collaborations in biomedical research and public health are far-reaching and continue to grow. The National Institutes of Health (NIH) has provided funding to over 150 research projects, and the recipients of these peer-reviewed grants are distributed throughout the country. The Centers for Disease Control and Prevention (CDC) is partnering with India in a wide variety of bilateral programs such as HIV/AIDS prevention, field epidemiology treatment and care, polio eradication, tobacco control, and control of tuberculosis. The Food and Drug Administration (FDA) routinely conducts inspections of Indian pharmaceutical facilities to ensure that products imported into the US meet stringent safety and efficacy standards. HHS maintains seven highly productive bilateral agreements with Government of India counterparts in the Ministry of Science and Technology and the Ministry of Health and Family Welfare.

By working together we are: 1) Developing new scientific knowledge in technology, 2) Developing and evaluating vaccines and drugs, and 3) Controlling, preventing and eradicating diseases. Over the past four decades, the HHS Office in New Delhi has participated in providing timely technical and policy advice on research and health issues in high priority areas such as HIV/AIDS, tuberculosis, malaria, polio, maternal and child health, tobacco control, environmental and occupational health, vaccine development, and emerging and re-emerging infectious diseases. The benefits from these collaborations flow back to the American people, but also to the Indian people and, through the goodwill generated on both sides, to the Indo-U.S. relationship in general.

— Dr. Altaf Lal, Health Attaché and HHS Regional Representative for South Asia, U.S. Embassy New Delhi

SEPTEMBER—DECEMBER HIGHLIGHTS

CDC Staff Participate in Regional JE Lab Network Training: In early October, SEARO held a regional Japanese Encephalitis (JE) Laboratory Network Training Workshop for Virologists. The JE Lab Network is similar to the polio and measles lab networks which support vaccine preventable disease surveillance in the region. For India, the GOI identified nine labs to be part of the network. Part of this funding is provided by DHHS/CDC/GID through the Global Disease Detection (GDD) project, through a grant/partnership with SEARO. SEARO has leveraged support from other partners including WHO/Headquarters and PATH to build the network. The lab training covered the use of a standardized ELISA kit for testing and reporting JE and Dengue.

CDC's Global AIDS Program: HHS/CDC is strongly committed to assisting India with its HIV/AIDS epidemic through President Bush's Emergency Plan for AIDS Relief (PEPFAR). The CDC-GAP-India Memorandum of Agreement with the Government of Tamil Nadu supports activities aimed at prevention, care and treatment, surveillance, training, and infrastructure development. The CDC/GAP held: 1) A Partner's Meeting in Chennai to review programs and provide technical update on HIV counseling and testing, 2) Provided technical assistance to NACO in the development of the USD 2.5 billion Phase 3 National Plan for HIV/AIDS and participated in technical working groups, including care and treatment, training, strategic information, monitoring and evaluation, 3) Drafted nursing curricula for HIV (NACO, U Washington, Clinton Foundation and WHO), and 4) Provided ongoing technical support for a training program on HIV/AIDS for women's self help groups in Tamil Nadu and two districts in Karnataka.

From the News Desk: HHS India for the first time held several bilateral Joint Working Groups back-to-back with a goal to enhance communication and productivity of bilateral Indo-US programs at the technical and policy level.

In the month of September, more than 50 U.S. scientists and officials traveled to participate in bilateral meetings.

SEPTEMBER WORK-SHOPS

National Consultative meeting on New Born Screening (Sept. 6-7)

Indo-U.S. Workshop on Hazardous Materials (Sept. 11-14)

Indo-U.S. Workshop on Maternal and Early Child Infections (Sept. 21-22)

Indo-U.S. Workshop on Translational Research Workshop (Sept. 25)

Meeting to establish NIH Alumni Association in India (Sept. 26)

Meeting on HIV/AIDS Bilateral Agreement (Sept. 27)

September Bilateral Joint Working Group (JWG) Meetings

Indo-U.S. Meeting on Emerging and Re-emerging Infectious Diseases and Disease Surveillance (ERRIDS): Under the auspices of HHS, the first ERRIDS meeting was held in New Delhi in September and the HHS delegation visited Pune, Chennai and Kolkata to discuss collaborations in emerging and re-emerging infectious diseases with emphasis on Avian Influenza. Some of the important outcomes of the HHS delegation visit were: 1) Establishment of a governance structure like a JWG, 2) Creation of a mechanism for rapid exchange of personnel and resources in case of outbreak and health emergencies, 3) Technical support for India's integrated disease surveillance program, 4) Enhance capacity building for clinical research and trials, and 5) Enhance collaboration on appropriate areas of research such as human and Avian Influenza.

Indo-U.S. JWG on Vaccine Action Program (VAP): The 20th JWG was held on September 26-27 to discuss future program priorities including a Rama-Robbins sponsored training program and workshops. Dr. V.S. Chauhan, Director ICGEB, delivered the 3rd Rama-Robbins lecture on "India Vaccine Hub—Reality or Mirage." The two sides agreed to collaborate on setting up translational research centers in India. The JWG appreciated the progress on Rotavirus, malaria vaccine projects, and a TB diagnostic project.

Indo-U.S. JWG on Contraceptive and Reproductive Health Research (CRHR): The 8th annual meeting held September 18-19 reviewed ten new proposals submitted in response to the annual call for applications plus two ad-hoc applications. Program priorities include future activities to increase training particularly in social/behavioral sciences and grants management, and innovative ideas on furthering contraception development in India.

Indo-U.S. JWG on Maternal and Child Health and Human Development Research (MCHDR): The 5th annual meeting and associated workshop on pediatric infectious diseases were held on September 21-22. The JWG reviewed fourteen new proposals and discussed possible plans to provide MCHDR sponsorship for a grant review and management training workshop and, as a follow-up to the one held this year, a workshop associated with next year's meeting focused on neonatal infections broadly with focus on specific needs to translate evidence to practice.

Indo-U.S. JWG on Expansion of Vision Research: The 1st JWG was held on September 28-29. The decision was made that the Government of India's Department of Biotechnology and HHS NEI will fund the joint research proposals. The priority project areas include genetic studies of special populations, clinical trials and development of research resources such as experimental animal facilities and diseased tissue banks.

SEPTEMBER-DECEMBER HIGHLIGHTS (CONTINUED)

Research Agenda Conference on Traditional Indian Medicine for HIV/AIDS: This meeting was organized in view of the need for a coordinated research plan to evaluate the use, efficacy, safety, and cost-effectiveness of Traditional Indian Medicine (TIM) for HIV/AIDS treatment in India. The four focus areas identified are: 1) Training, infrastructure and research methodology, 2) Effectiveness in research, 3) Observational research/epidemiology, and 4) Product safety. The next steps are to: 1) Codify the steering committee, 2) Select an advisory committee of 6-8 top scientists, 3) In collaboration with EdSearch and Sassoon General Hospitals conduct a qualitative study to document the role of TIM in HIV/AIDS management and treatment in Pune, 4) Publish in relevant journals the conference proceedings, 5) Plan yearly meetings of the steering and advisory committees, 6) Target international funding organizations for support through the development of a comprehensive and collaborative proposal, and 7) Craft this research agenda into a practical roadmap for future research on TIM for HIV/AIDS.

Polio Watch

The downward trend of polio cases during the last two years in India led to optimism that eradication of polio was imminent. Although the number of polio cases has increased in 2006, that optimism remains at the technical, policy and political level in India. The 2006 polio outbreak originated in Moradabad and surrounding districts in west Uttar Pradesh (UP). The outbreak strain of poliovirus from UP has spread during the current high transmission season to additional States that include Maharashtra, Madhya Pradesh, Chandigarh and West Bengal that were polio free since 2004. The current increase in cases is due to an increase in the number of children missed in vaccination campaigns in west UP during the second half of 2005. Several of the affected west UP districts had eliminated transmission individually during the past 2-3 years, but had not done this collectively; this led to re-infection of areas that had become polio free. A number of corrective measures have been put in place resulting in much improved quality and consistency of campaigns and decline in the incidence of polio in west UP.

2006 UPDATE (WHO/SEARO, Jan 22, 2007; WHO/EMRO, Jan 22, 2007)

Bangladesh : No new polio case reported Week #3 2007. Date of most recent polio case 4-Nov-2006 reported from district Habiganj, Sylhet division. Total polio cases in 2006 = 17.

India : Twelve new polio cases reported Week #3 2007. Date of most recent polio case 17-Dec-2006 reported from district Azamgarh, Uttar Pradesh. Total wild polio cases in 2006 = 660.

Nepal : Two new polio cases reported from Nepal reported Week #3 2007. Date of most recent polio case 23-Oct-2006, reported from Rautahat district in CDR region. Total polio cases in 2006 = 4.

Pakistan : Thirty nine polio cases reported in 2006. In November, confirmed polio cases = 6 reported Week #2 2007.

SEPTEMBER-DECEMBER HIGHLIGHTS (CONTINUED)

U.S. Supports Program to Fight Tuberculosis in India: U.S. Ambassador to India, David C. Mulford, and the World Health Organization (WHO) representative to India Dr. Salim Habayeb signed on September 26 in New Delhi a joint agreement for tuberculosis control in India. The USAID provided to the WHO USD 4.17 million for research and state level implementation of the national disease control program.

National Symposium on Tribal Health: A National Symposium on Tribal Health was held on October 19-20 at the Regional Medical Research Centre for Tribals (RMRCT) at Jabalpur. The symposium focused on various aspects of tribal health in the area of communicable and non-communicable diseases.

Clinical Trials Workshop: Pharmaceutical, Biotech Product Development & Clinical Research: The Need for a World-Class Regulatory Environment in India, October 26-27, New Delhi. The workshop is the third in a series of workshops on clinical research and clinical trials funded by the Office of AIDS Research, NIH. The previous workshops were on technical issues in randomized controlled trials and bioethics. The aim in the September workshop was to discuss a way to streamline the current clinical research regulations in India to make them compatible with the internationally recognized regulatory environment. Some major recommendations include: 1) Provide a single-window clearance of all clinical trial applications, and web-based communications between applicants and regulators during entire approval process, 2) Adopt fixed time lines for processing applications, 3) Develop a web-based, regularly updated guidance document for applicants, 4) Customize existing guidelines (e.g. ICH) and adapt them to India's needs, 5) Build capacity by increasing number of reviewers, scientific experts and support staff in the government regulatory agency, 6) Strengthen reviewers expertise through a continued training program, 7) Decrease application turn-around time by charging user fees, and 8) Develop enforcement mechanisms to guarantee compliance to regulations and a level play field for applicants.

Expanding Indo-U.S. Collaboration in the Fight Against Avian Influenza

October 2006 — U.S. Embassy Charge d'Affaires Geoff Pyatt signed grant agreements on behalf of HHS/CDC with the World Health Organization (WHO), the Indian Council of Medical Research (ICMR) and the International Center for Genetic Engineering and Biotechnology (ICGEB), which will support a series of workshops on Avian Influenza in India. At the signing ceremony, CDA Geoff Pyatt said "he was pleased that the US government is able to play a significant role in tackling this worldwide public health problem."

CDC is supporting the ICMR in multi-center surveillance for human and avian influenza surveillance in India. Funding support for the series of workshops will enhance our joint capacity to detect and respond to avian influenza.

Preparedness is the key to substantially reducing the health, social and economic impacts of an influenza pandemic and other public health emergencies.



U.S. Embassy Charge d'Affaires Geoff Pyatt (left) signed a grant agreement with Dr. Salim Habayeb, the WHO representative to India, on Friday, October 13, 2006. (Photocredit: U.S. Embassy New Delhi)



U.S. Embassy Charge d'Affaires Geoff Pyatt (left) signed a grant agreement with Dr. N.K. Ganguly, Director General of the Indian Council of Medical Research, on Friday, October 13, 2006. (Photocredit: U.S. Embassy New Delhi)



U.S. Embassy Charge d'Affaires Geoff Pyatt (left) signed a grant agreement with Dr. V.S. Chauhan of the ICGEB on Thursday, October 12, 2006. (Photocredit: U.S. Embassy New Delhi)

The Workshops will aim to strengthen human capacity for influenza surveillance and response for early warning, verification, reporting, investigation and response to outbreaks of Avian Influenza.

TB PROGRAM IN INDIA

In October 2006, the Government of India invited an international panel of experts from the fields of public health, TB research and treatment, medical education and other related sectors, to visit the country and participate in the Joint Monitoring Mission (JMM). This is the third such JMM to review the Revised National Tuberculosis Control Program (RNTCP). Tuberculosis and health systems experts from HHS participated in the JMM.

For over two weeks, members of the JMM visited 20 randomly selected districts in six states. They interacted with national, state and district level authorities, extensively reviewed patient records, and interviewed patients and program staff.

The JMM observed that the Indian TB Control program has successfully completed the largest and most rapid expansion of Directly Observed Treatment Short Course (DOTS) in history to cover the entire country. As a result, in 2004 the RNTCP accounted for over a fifth of all TB cases treated worldwide.

The JMM further found that the program is very effective and in many ways is a model for other health programs, including the availability of microscopy services for diagnosis, reliable supplies of good quality drugs and a transparent and powerful reporting system. The rapid expansion of services and scale of activities have, however, stretched the capacity of the health system. The JMM therefore recommended steps to strengthen the core capacity for program implementation at central and state levels. These steps included strengthening the responses to the growing challenges of drug-resistant tuberculosis and tuberculosis among HIV-infected persons, who are particularly vulnerable to the disease.

The JMM observed that if the RNTCP continues its current impetus and effectively undertakes the necessary additional interventions, India should achieve the TB targets set under the Millennium Development Goals.

SEPTEMBER-DECEMBER HIGHLIGHTS (CONTINUED)

Centers for Disease Control and Prevention (CDC) Director Dr. Julie Louise Gerberding delivered the Inaugural Address, December 18, 2006, at the University of Hyderabad International Workshop on Defining the Future – HIV/AIDS – Next 25 Years. The event marked the 25th anniversary of the documentation of the first case of HIV by CDC. “I am pleased to accept your invitation to speak at this forum, which strongly signals that the University and India as a country are looking to the future of HIV and are taking all necessary steps to achieve success in HIV/AIDS prevention, treatment, and care,” Dr. Gerberding said in accepting the opportunity to speak. The focus areas of the Hyderabad conference, which is in part supported by the U.S. Department of Health and Human Services (HHS), parent agency of CDC, were prevention, treatment and care, development of vaccines, pediatric AIDS, access to antiretroviral drugs, clinical research, diagnosis and other scientific and public health aspects of HIV/AIDS.

Also on December 18, the CDC Director met with the health professionals of the Women’s Self Help Group initiative, a primary health care center enhancement project of the Catholic Hospital Association of India (CHAI), which is supported in-part by CDC’s Global AIDS Program (GAP).

On December 19 in New Delhi, Dr. Gerberding represented the HHS/CDC at the Round Table meetings on polio eradication and health policy organized by the Ministry of Health and Family Welfare. CDC collaborates with several Indian institutions on human and Avian Influenza, malaria, TB, polio eradication, HIV/AIDS, tobacco control, environmental and occupational health, and field epidemiology and laboratory strengthening for disease outbreak responses. Also, in New Delhi, Dr. Gerberding met with officials of the Ministry of Health, Ministry of Agriculture, the Indian Council of Medical Research, the National Institute of Communicable Diseases, National AIDS Control Organization, and WHO/SEARO for discussion of ongoing collaborations.

On December 21, Dr. Gerberding visited the National Institute of Virology to review that organization’s ongoing collaboration with CDC on avian and human influenza, disease outbreak and other emerging and re-emerging infectious diseases.

Other Workshops held:

- ◆ ICMR and WHO organized Workshop on Pesticide Residues and Their Risk Assessment, New Delhi, November 2006
- ◆ Workshop to develop strategy for HIV management tool-kit, Chennai, November 2006
- ◆ Asian Pacific Conference on Medical Virology, New Delhi, November 2006
- ◆ Indo-U.S. Workshop on Viral Diagnostics, Epidemiology and Pathogenesis, New Delhi, November 2006
- ◆ SEARO: India Expert Polio Advisory Group Meeting, New Delhi, December 2006

MINISTRY OF HEALTH NEW APPOINTMENTS

New Drugs Controller General of India Takes Charge: Dr. M. Venkateswarlu became the Drugs Controller General of India (DCGI) on September 1 in New Delhi. Earlier, Dr. Venkateswarlu was Deputy Drugs Controller of India (west zone) and replaces Dr. Ashwini Kumar, who has retired.

New Secretary in the Ministry of Health and Family Welfare: Mr. Naresh Dayal took charge as Secretary in the Ministry of Health and Family Welfare, Government of India. He replaces Mr. Prasanna Hota who has retired.

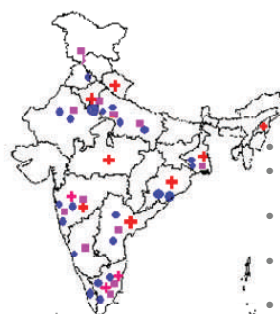
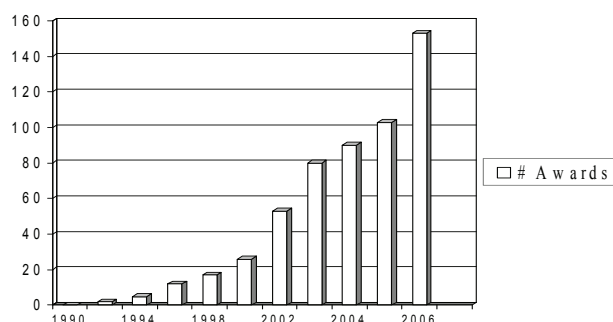
SUMMARY OF INDIA ACTIVITIES—HHS AGENCIES WORK IN INDIA

The National Institutes of Health (NIH): NIH has provided funding to over 150 research projects in India, a marked increase from zero in 1990, 17 in 1998, and 67 at the beginning of 2003. Recipients of these peer-reviewed grants are distributed throughout the country and cover a wide range of cutting edge research priorities. NIH builds research capacity and collaborative opportunities in India through investigator-initiated grants, direct financial and technical support for a primate research center in Mumbai, an International Center for Excellence in Tuberculosis Research in Chennai, targeted workshops and training activities, and postdoctoral research training in the U.S. for over 150 Indian scientists.

The Centers for Disease Control and Prevention (CDC): CDC is partnering with India in a wide variety of bilateral programs. CDC's extensive polio eradication efforts make it one of the largest supporters of polio eradication efforts in India. Through HHS' Global AIDS Program (GAP), CDC is strongly committed to providing support for Government of India efforts to control the country's HIV epidemic. CDC provides substantial technical support for India's national efforts to prevent and treat Tuberculosis. CDC provided technical and financial support for the preparation of India's report on Tobacco Control, which was published in 2004. CDC is also collaborating on TB, Malaria and Avian Influenza and other high priority diseases. The CDC is supporting the Field Epidemiology Training Program (FETP) at Chennai through technical consultations from CDC and by posting a resident advisor.

Food and Drug Administration (FDA): Regulatory inspection staff from FDA routinely conduct inspections of Indian pharmaceutical facilities to ensure that products imported into the U.S. meet stringent safety and efficacy standards. FDA scientists also collaborate with Indian scientists on infectious disease research. As a part of President Bush's Emergency Plan for HIV/AIDS relief, FDA is working closely with finished dose and Active Pharmaceutical Ingredient (API) producers in India to expedite the review of generic antiretroviral drugs for the treatment of HIV/AIDS. FDA's expedited review of drug products from the pharmaceutical industry in India is critical to the overall success of the President's Emergency Plan for HIV/AIDS relief, since India produces a large portion of the available supply of generic antiretroviral HIV/AIDS drugs.

NIH Awards in India



HHS ACTIVITIES IN INDIA
 • NIH
 • CDC
 • RECENT WORKSHOPS

PRODUCTS OF COLLABORATION INDIA

- Progress towards polio elimination
- Enhance activities on HIV/AIDS research and prevention programs
- Increase knowledge of infectious and chronic disease systems
- Collaborative development of vaccines for rotavirus, HIV, etc
- Public-private partnerships in drug and vaccine development
- Health Systems Development
- Health Product Development

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We welcome your comments/suggestions/inputs

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